Docket No. 246424US8

### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

GAU:

IN RE APPLICATION OF: Thomas NILSSON, et al.

SERIAL NO: New Application

FILED: Herewith EXAMINER:

FOR: A MEDICAL PRODUCT

## **INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR 1.97**

COMMISSIONER FOR PATENTS ALEXANDRIA, VIRGINIA 22313

SIR

Applicant(s) wish to disclose the following information.

#### REFERENCES

- The applicant(s) wish to make of record the references listed on the attached form PTO-1449. Copies of the listed references are attached, where required, as are either statements of relevancy or any readily available English translations of pertinent portions of any non-English language references.
- ☐ A check or credit card payment form is attached in the amount required under 37 CFR §1.17(p).

#### RELATED CASES

- Attached is a list of applicant's pending application(s) or issued patent(s) which may be related to the present application. A copy of the patent(s), together with a copy of the claims and drawings of the pending application(s) is attached along with PTO 1449.
- A check or credit card payment form is attached in the amount required under 37 CFR §1.17(p).

#### **CERTIFICATION**

- ☐ Each item of information contained in this information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this statement.
- □ No item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to the knowledge of the undersigned, having made reasonable inquiry, was known to any individual designated in 37 CFR §1.56(c) more than three months prior to the filing of this statement.

### DEPOSIT ACCOUNT

Please charge any additional fees for the papers being filed herewith and for which no check or credit card payment is enclosed herewith, or credit any overpayment to deposit account number <u>15-0030</u>. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

OBLON, SRIVAK, McCLELLAND, MAIER & YEUSTADT, P.C.

Bradley D. Lytle

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## **STATEMENT OF RELEVANCY**

Reference AW listed on the attached Form PTO 1449 is discussed at page 4, lines 22-25 of the specification.

Reference AX listed on the attached Form PTO 1449 is discussed at page 5, lines 8-11 of the specification.

Reference AY listed on the attached Form PTO 1449 is discussed at page 5, lines 11-13 of the specification.

Form PTO 1449 (Modified)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY DOCKET NO.		SERIAL NO. New Application		
				246424US8				
LIST OF REFERENCES CITED BY APPLICANT				APPLICANT				
				Thomas NILSSON, et al.				
				FILING DATE		GROUP		
				lerewith				
U.S. PATENT DOCUMENTS								
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	S SUB FILING DATE IF APPROPRIATE		
	AA							
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FOREIGN PATENT DOCUMENTS								
		DOCUMENT NUMBER	DATE	COUNTRY		TRANS YES		SLATION NO
	AO							
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	AT							
	AU							
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OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, etc.)								
	COLLEGE TER BEOORDELING VAN GENEESMIDDELEN MEDICINES EVALUATION BOARD; PUBLIC ASSESSMENT AW REPORT; "Spiriva 18 μg, inhalation powder in hard capsules"; May 21, 2002; pp. 1-28							
	AX	Guidance for Industry; "Metered Dose Inhaler (MDI) and Dry Powder Inhaler (DPI) Drug Products"; Chemistry, Manufacturing, and Controls Documentation; 1998						
	AY	Guidance for Industry; "Stability Testing of Drug Substrances and Drug Products"; Draft Guidance B; 1998						
	AZ		Additional References sheet(s) attached					
Examiner					Date Considered			
				t citation is in conformance with MPEP 60 n with next communication to applicant.	9; Draw li	ne through	citation	if not in